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510(k) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the Sulzer Orthopedics MS-30 Lateral Femoral Stem.

Manufacturer:	Sulzer Orthopedics Ltd. Grabenstrasse 25 CH 6341 Baar, Switzerland
US Designated Agent:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Date:	April 15, 2002
Contact Person:	Frances E. Harrison, RAC Manager, Regulatory Projects
Classification Name:	21 CFR Part 888.3353 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Common/Usual Name:	Cemented Femoral Stem Component
Trade/Proprietary Name:	Sulzer Orthopedics MS-30 Lateral Femoral Stem

PRODUCT DESCRIPTION

MS-30 Lateral Femoral Stem

The MS-30 Lateral Femoral Stem intended for cemented use, is a highly polished, collarless femoral component manufactured from forged stainless steel (Protasul S-30, ISO 5832-9). The lateral version offers the surgeon 12% more offset than with the standard version. The stem features a three dimensional conical wedge shape with rounded edges to aid in rotational stability, self-centering in the femoral canal and creation of a favorable cement mantle. The proximal portion of the stem has a male 12/14 taper for attachment of a Sulzer Orthopedics metallic or ceramic femoral head with a neck that accepts an optional Proximal Positioner. The distal portion is designed to accept the optional existing and new Distal Centralizer. It is available in six sizes.

Distal Centalizer

The optional new distal centralizer manufactured from Sulene -PMMA (poly-methyl-meth-acrylate/poly-styrene, ISO 5833-1), is intended for use with the MS-30 Standard and Lateral Femoral Stems. The centralizer is conically shaped and designed with four wings for better centering of the stem within the diaphysis of the femur providing a favorable cement mantle. One of the wings is longer than the others indicating its position on the lateral side of the stem. It is offered in two sizes for each of the six stem sizes.

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Proximal Positioner (Centralizer)

The MS-30 also features an optional proximal positioner which is manufactured from Sulene – PMMA. The proximal positioner, intended for cemented use, centers the femoral stem in the anterior/posterior plane. It inserts into the extraction hole and snaps onto the neck of the stem. Once the bone cement has polymerized, the upper portion of the positioner is removed leaving the cemented U-shaped portion creating a favorable cement mantle.

SPECIFIC DIAGNOSTIC INDICATIONS

The MS-30 Lateral Femoral Stem is intended for cemented use in treatment of the following:

1. Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.

2. Those patients with failed previous surgery where pain, deformity, or dysfunction persists.

3. Revision of previously failed hip arthroplasty.

SUBSTANTIAL EQUIVALENCE

The MS-30 Lateral Femoral Stem is similar to the following commercially available devices in terms of intended use, materials and general design:

- MS-30 Femoral Stem, Centralizer
- Howmedica Osteonics Exeter Hip Stem, Centralizer
- Howmedica Osteonics Definitions Stem
- Zimmer VerSys Hip Cemented CT Hip Stem, Centralizer

Analysis indicated that the device would survive physiologic loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2002

Ms. Frances E. Harrison, RAC
Manager, Regulatory Projects
Sulzer Orthopedics, Inc.
9900 Spectrum Drive
Austin, TX 78717

Re: K020713
Trade/Device Name: MS-30 Lateral Femoral Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LZO
Dated: March 1, 2002
Received: March 5, 2002

Dear Ms. Harrison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

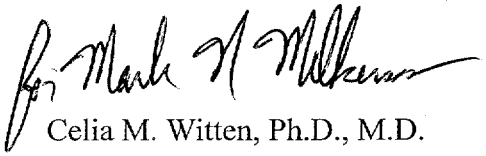
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (K020713):

Device Name: MS-30™ Lateral Femoral Stem

Indications For Use:

The MS-30 Lateral Femoral Stem is intended for cemented use in treatment of the following:

1. Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.

2. Those patients with failed previous surgery where pain, deformity, or dysfunction persists.

3. Revision of previously failed hip arthroplasty.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use

(Optional Format 1-2-96)

for Mark N. Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020713 MNM
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